

**Notice of Allowability**

Application No.

10/674,268

Examiner

Rosanne Kosson

Applicant(s)

FANTUZZI, MICHAEL

Art Unit

1653

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to an amendment filed on June 7, 2005.
2. ☒ The allowed claim(s) is/are 1,2,5-15,18-20,22,23 and 25-51.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 2/25 & 7/1/05
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows.

The claims have been amended as follows.

1. (Currently amended) A composition comprising:  
coenzyme Q-10 ~~or an analog thereof~~, a sufficient quantity of limonene suitable to solubilize said coenzyme Q-10; and an acceptable carrier.
2. (Currently amended) The composition of claim 1, wherein said coenzyme Q-10 ~~or an analog thereof~~ is selected from the group consisting of coenzyme Q-10, reduced coenzyme Q-10 and semi-reduced coenzyme Q-10.
3. (Canceled)
4. (Canceled)
5. (Original) The composition of claim 1, wherein said composition is in the form of a solution, an elixir, a suspension, or a caplet.
6. (Original) The composition of claim 5, wherein said caplet is a soft gelatin tablet.
7. (Original) The composition of claim 6, wherein said soft gelatin tablet further comprises rice bran oil or beeswax.

Art Unit: 1653

8. (Currently amended) The composition of claim 1, wherein said coenzyme Q-10 ~~or analog thereof~~ is solubilized in said limonene in an amount of at least about 0.1 % by weight to about 45% by weight at room temperature.

9. (Currently amended) The composition of claim 1, wherein said coenzyme Q-10 ~~or analog thereof~~ is solubilized in said limonene in an amount of least about 5% to about 40% by weight at room temperature.

10. (Original) The composition of claim 1, further comprising vitamin E.

11. (Original) The composition of claim 1, further comprising a seed oil.

12. (Previously Presented) The composition of claim 1, further comprising a fish oil.

13. (Original) The composition of claim 1, further comprising an antioxidant.

14. (Currently amended) A soft gelatin capsule, comprising at least 5% by weight of coenzyme Q-10 ~~or an analog thereof~~ solubilized in limonene.

15. (Currently amended) The soft gelatin capsule of claim 14, wherein said coenzyme Q-10 ~~or analog thereof~~ is selected from the group consisting of coenzyme Q-10, reduced coenzyme Q-10 and semi-reduced coenzyme Q-10.

16. (Canceled)

17. (Canceled)

18. (Previously Presented) The soft gelatin capsule of claim 14, wherein said coenzyme Q-10 is solubilized in said limonene in an amount of about 10 percent to about 40 percent by weight.

19. (Original) The composition of claim 14, wherein said soft gelatin tablet further comprises rice bran oil or beeswax.

Art Unit: 1653

20. (Original) The composition of claim 14, wherein said soft gelatin tablet further comprises an antioxidant.

21. (Canceled)

22. (Currently amended) A packaged nutraceutical formulation comprising:  
coenzyme Q-10 ~~or an analog thereof~~, and a sufficient quantity of limonene  
suitable to solubilize said coenzyme Q-10, wherein said formulation is encapsulated in a  
gelatin capsule; and instructions for use thereof.

23. (Currently amended) The packaged nutraceutical formulation of claim 22, wherein said  
coenzyme Q-10 ~~or an analog thereof~~ is selected from the group consisting of coenzyme Q-  
10, reduced coenzyme Q-10 and semi-reduced coenzyme Q-10.

24. (Canceled)

25. (Currently amended) The composition of claim 1, wherein said coenzyme Q-10 or  
analog thereof, is solubilized in said limonene in an amount from about 30 to about 45  
percent by weight.

26. (Currently amended) The composition of claim 1, wherein said coenzyme Q-10 ~~or  
analog thereof~~, is solubilized in said limonene in an amount from about 15 to about 40  
percent by weight.

27. (Currently amended) The composition of claim 1, wherein said coenzyme Q-10 ~~or  
analog thereof~~, is solubilized in said limonene in an amount from about 5 to about 50  
percent by weight.

28. (Previously Presented) The composition of claim 1, wherein said carrier is an oil.

29. (Previously Presented) The composition of claim 28, wherein said oil is rice bran oil.

30. (Previously Presented) The composition of claim 28, wherein said oil is a fish oil.

Art Unit: 1653

31. (Previously Presented) The composition of claim 28, further comprising a tocopherol.

32. (Currently amended) The soft gelatin capsule of claim 14, wherein said coenzyme Q-10 ~~or analog thereof~~ is solubilized in said limonene in an amount from about 30 to about 45 percent by weight.

33. (Currently amended) The soft gelatin capsule of claim 14, wherein said coenzyme Q-10 ~~or analog thereof~~, is solubilized in said limonene in an amount from about 15 to about 40 percent by weight.

34. (Currently amended) The soft gelatin capsule of claim 14, wherein said coenzyme Q-10 ~~or analog thereof~~, is solubilized in said limonene in an amount from about 5 to about 50 percent by weight.

35. (Canceled)

36. (Currently amended) The soft gelatin capsule of claim 14, wherein said coenzyme Q-10 ~~or analog thereof~~, is solubilized in said limonene in an amount from about 0.1 to about 45 percent by weight.

37. (Previously Presented) The soft gelatin capsule of claim 14, further comprising a carrier.

38. (Previously Presented) The soft gelatin capsule of claim 37, wherein said carrier is an oil.

39. (Previously Presented) The soft gelatin capsule of claim 38, wherein said oil is rice bran oil.

40. (Previously Presented) The soft gelatin capsule of claim 38, wherein said oil is a fish oil.

41. (Previously presented) The soft gelatin capsule of claim 38, further comprising a tocopherol.

Art Unit: 1653

42. (Currently amended) The packaged nutraceutical formulation of claim 22, wherein said coenzyme Q-10 ~~or analog thereof~~, is solubilized in said limonene in an amount from about 30 to about 45 percent by weight.

43. (Currently amended) The packaged nutraceutical formulation of claim 22, wherein said coenzyme Q-10 ~~or analog thereof~~, is solubilized in said limonene in an amount from about 15 to about 40 percent by weight.

44. (Currently amended) The packaged nutraceutical formulation of claim 22, wherein said coenzyme Q-10 ~~or analog thereof~~, is solubilized in said limonene in an amount from about 5 to about 50 percent by weight.

45. (Currently amended) The packaged nutraceutical formulation of claim 22, wherein said coenzyme Q-10 or analog thereof is solubilized in said limonene in an amount from about 5 to about 50 percent by weight.

46. (Currently amended) The packaged nutraceutical formulation of claim 22, wherein said coenzyme Q-10 ~~or analog thereof~~, is solubilized in said limonene in an amount from about 0.1 to about 45 percent by weight.

47. (Currently amended) The packaged nutraceutical formulation of claim 22, wherein said formulation further comprises ~~comprising~~ a carrier.

48. (Previously Presented) The packaged nutraceutical formulation of claim 47, wherein said carrier is an oil.

49. (Previously Presented) The packaged nutraceutical formulation of claim 48, wherein said oil is rice bran oil.

50. (Previously Presented) The packaged nutraceutical formulation of claim 48, wherein said oil is a fish oil.

Art Unit: 1653

51. (Previously Presented) The packaged nutraceutical formulation of claim 48, further comprising a tocopherol.

Claim 35 has been canceled because it is a duplicate of claim 34.

2. The following is an examiner's statement of reasons for allowance. The prior art neither teaches nor suggests a composition comprising coenzyme Q-10 in which the coenzyme Q-10 is dissolved in limonene. Garti et al. (US 2003/0232095) disclose compositions comprising coenzyme Q-10, limonene and a carrier, but these three components are blended to create nano-sized, self-assembled, structured concentrates in which the coenzyme Q-10 is solubilized in the limonene phase, and the concentrate is maintained as one phase by the presence of a surfactant. The coenzyme Q-10 is not first dissolved in limonene to which a carrier is added (see paragraphs 29, 30 and 40-42). Additionally, Applicant defines carrier as an oil, fat or capsule. Applicant's compositions have no aqueous phase.

Authorization for this amendment was given by Applicant's representative, Mr. Scott Rothenberger, on August 11, 2005.

3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Art Unit: 1653

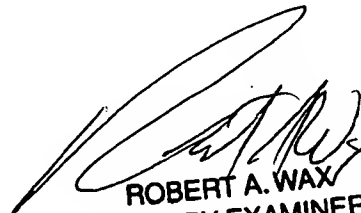
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson  
Examiner  
Art Unit 1653

rk/2005-08-11



ROBERT A. WAX  
PRIMARY EXAMINER